In the Claims

Please amend the claims by replacing all prior versions, and listings, of claims pursuant to 37 C.F.R. §1.121(c) as follows:

1-122. (Canceled)

123. (Currently Amended) In a process for obtaining a pharmaceutical product containing a mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, wherein the mixture has an average molecular weight from 4000 to 13,000 Daltons and in the mixture the molar fraction of alanine is 0.427, of glutamic acid is 0.141, of lysine is 0.337 and of tyrosine is 0.093 and wherein ~~during~~ the process includes determining the molecular weight distribution of a batch of ~~a~~ an aqueous mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, ~~is tested~~ using a gel permeation chromatography column to determine whether the mixture has an average molecular weight from 4000 to 13,000 Daltons for inclusion in the pharmaceutical product, the improvement comprising

calibrating the molecular weight obtained using the gel permeation chromatography column by subjecting a plurality of molecular weight markers, each of which is a polypeptide consisting essentially of alanine, glutamic acid, tyrosine and lysine and having a predetermined amino acid sequence, to chromatography on the column to establish a relationship between retention time on the column and molecular weight.

124-126. (Canceled)

127. (Previously presented) The process of claim 123, wherein the gel permeation chromatography column comprises a cross-linked agarose-based medium, with an exclusion limit of 2 x 10^6 Daltons, an optimal separation range of 1000 to 3x 10^5 Daltons, and a bead diameter of 20-40 μm.

128. (Previously presented) The process of claim 127, wherein the gel permeation chromatography column is Superose 12.

129. (Previously amended) The process of claim 123, wherein in the molecular weight markers the molar fraction of alanine is 0.38 to 0.5, of glutamic acid is 0.13 to 0.15, of tyrosine is 0.08 to 0.10 and of lysine is 0.3 to 0.4.

130. (Previously Amended) The process of claim 129, wherein in the molecular weight markers the molar fraction of alanine is 0.422 to 0.444, of glutamic acid is 0.133 to 0.143, of tyrosine is 0.086 to 0.093 and of lysine is 0.333 to 0.349.

131. (Previously presented) The process of claim 123, wherein one of the molecular weight markers is selected from the group consisting of

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);

AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYE A (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAA KAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA AAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA AAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and
AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAK AKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA (SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.

132. (Previously presented) The process of claim 123, wherein the plurality of molecular weight markers is

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYE A (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAA KAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA AAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA AAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and
AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAK AKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA (SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.

133. (Previously Amended) The process of claim 123, wherein the pharmaceutical product is lyophilized.

134. (Previously Amended) A process for obtaining a pharmaceutical product containing a mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, wherein the mixture has an average molecular weight from 4000 to 13,000 Daltons and in the mixture the molar fraction of alanine is 0.427, of glutamic acid is 0.141, of lysine is 0.337 and of tyrosine is 0.093, which comprises obtaining a batch of a mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine;

determining the average molecular weight of the mixture of polypeptides in the batch using a molecular weight-calibrated gel permeation chromatography column; and

including in the pharmaceutical product the mixture if the mixture is determined to have an average molecular weight from 4000 to 13,000 Daltons,

wherein the gel permeation chromatography column is calibrated by subjecting a plurality of molecular weight markers to chromatography on the column to establish a relationship between the retention time on the column and molecular weight, wherein each of the markers is a polypeptide consisting essentially of

alanine, glutamic acid, tyrosine and lysine and has a predetermined amino sequence.

135-137. (Canceled)

138. (Previously presented) The process of claim 134, wherein the gel permeation chromatography column comprises a cross-linked agarose-based medium, with an exclusion limit of 2 x 10^6 Daltons, an optimal separation range of 1000 to 3x 10^5 Daltons, and a bead diameter of 20-40 μm.

139. (Previously presented) The process of claim 138, wherein the gel permeation chromatography column is Superose 12.

140. (Previously Amended) The process of claim 134, wherein in the molecular weight markers the molar fraction of alanine is 0.38 to 0.5, of glutamic acid is 0.13 to 0.15, of tyrosine is 0.08 to 0.10 and of lysine is 0.3 to 0.4.

141. (Previously Amended) The process of claim 140, wherein in the molecular weight markers the molar fraction of alanine is 0.422 to 0.444, of glutamic acid is 0.133 to 0.143, of tyrosine is 0.086 to 0.093 and of lysine is 0.333 to 0.349.

142. (Previously presented) The process of claim 134, wherein one of the molecular weight markers is selected from the group consisting of

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYAAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYAAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and
AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAKAKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA (SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.

143. (Previously presented) The process of claim 134, wherein the plurality of molecular weight markers is

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYAAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYAAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and

AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAK AKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA (SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.

144. (Currently Amended) The process of claim 134, further comprising a step of lyophilizing the mixture ~~having the average molecular weight from 4,000 to 13,000 Daltons~~ of polypeptides.

145. (Previously Amended) A process for determining the average molecular weight of an aqueous mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, wherein in the mixture the molar fraction of alanine is 0.427, of glutamic acid is 0.141, of lysine is 0.337 and of tyrosine is 0.093, which comprises subjecting the mixture to chromatography on a molecular weight-calibrated gel permeation chromatography column so as to determine the average molecular weight of the mixture, wherein the gel permeation chromatography column is calibrated by subjecting a plurality of molecular weight markers to chromatography on the column to establish a relationship between retention time on the column and molecular weight, wherein each of the markers is a polypeptide consisting essentially of alanine, glutamic acid, tyrosine and lysine and has a predetermined amino acid sequence.

146-148. (Canceled)

149. (Previously presented) The process of claim 145, wherein the gel permeation chromatography column comprises a cross-linked agarose-based medium, with an exclusion limit of 2 x 10^6 Daltons, an optimal separation range of 1000 to 3x 10^5 Daltons, and a bead diameter of 20-40 μm.

150. (Previously presented) The process of claim 149, wherein the gel permeation chromatography column is Superose 12.

151. (Previously Amended) The process of claim 145, wherein in the molecular weight markers the molar fraction of alanine is 0.38 to 0.5, of glutamic acid is 0.13 to 0.15, of tyrosine is 0.08 to 0.10 and of lysine is 0.3 to 0.4.

152. (Previously Amended) The process of claim 151, wherein in the molecular weight markers the molar fraction of alanine is 0.422 to 0.444, of glutamic acid is 0.133 to 0.143, of tyrosine is 0.086 to 0.093 and of lysine is 0.333 to 0.349.

153. (Previously presented) The process of claim 145, wherein one of the molecular weight markers is selected from the group consisting of

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);

AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYE
A (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAA
KAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA
AAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA
AAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and
AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAK
AKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA
(SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.

154. (Previously presented) The process of claim 145, wherein the plurality of molecular weight markers is

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYE
A (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAA
KAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA
AAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA
AAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and
AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAK
AKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA
(SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.

155. (Previously Amended) A process for determining whether an aqueous mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, has an average molecular weight from 4000 to 13,000 Daltons, wherein in the mixture the molar fraction of alanine is 0.427, of glutamic acid is 0.141, of lysine is 0.337 and of tyrosine is 0.093, which process comprises subjecting the mixture to a calibrated gel permeation chromatography column to determine the average molecular weight of the mixture wherein the gel permeation chromatography column is calibrated by subjecting a plurality of molecular weight markers to chromatography on the column to establish a relationship between retention time on the column and molecular weight, wherein each of the markers is a polypeptide consisting essentially of alanine, glutamic acid, tyrosine and lysine and has a predetermined amino acid sequence.

156-158. (Canceled)

159. (Previously presented) The process of claim 155, wherein the gel permeation chromatography column comprises a cross-linked agarose-based medium, with an exclusion limit of 2×10^6 Daltons, an optimal separation range of 1000 to 3×10^5 Daltons, and a bead diameter of 20-40 μm.

160. (Previously presented) The process of claim 159, wherein the gel permeation chromatography column is Superose 12.

161. (Previously amended) The process of claim 155, wherein in the molecular weight markers the molar fraction of alanine is 0.38 to 0.5, of glutamic acid is 0.13 to 0.15, of tyrosine is 0.08 to 0.10 and of lysine is 0.3 to 0.4.

162. (Previously amended) The process of claim 161, wherein in the molecular weight markers the molar fraction of alanine is 0.422 to 0.444, of glutamic acid is 0.133 to 0.143, of tyrosine is 0.086 to 0.093 and of lysine is 0.333 to 0.349.

163. (Previously presented) The process of claim 155, wherein one of the molecular weight markers is selected from the group consisting of

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and

AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAK AKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA (SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.

164. (Previously presented) The process of claim 155, wherein the plurality of molecular weight markers is

AKKYAKKEKAAKKAYKKEAKAKAAEAAAKEAAYEA (SEQ ID NO:1);
AKKYAKKAKAEKAKKAYKAAEAKKAAKYEKAAAEKAAAKEAAYEA (SEQ ID NO:2);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAEAKYKAEAAKAAAKEAAYE A (SEQ ID NO:3);
AKKYAKKEKAYAKAKKAEAKAAKKAKAEAKKYAKAAKAEKKEYAAAEAKYKAEAA KAAAKEAAYEA (SEQ ID NO:4);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA AAEAKYKAEAAKAAAKEAAYEA (SEQ ID NO:5);
AKKYAKKEKAYAKKAEKAAKKAEAKAYKAAEAKKKAKAEAKKYAKAAKAEKKEYA AAEAKYKAEAAKKAYKAEAAKAAAKEAAYEA (SEQ ID NO:6); and
AKKYAKKAEKAYAKKAKAAKEKKAYAKKEAKAYKAAEAKKKAKAEAKKYAKEAAK AKKEAYKAEAKKYAKAAKAEKKEYAAAEAKKAEAAKAYKAEAAKAAAKEAAYEA (SEQ ID NO:7),

wherein A represents alanine, K represents lysine, Y represents tyrosine, and E represents glutamic acid.